Remarks

Claims 25-36 and 47-56 are pending in the instant application.

Applicants have canceled claims 1, 8, 13, 15, 17-21, 23 and 37-46 without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in one or more continuing applications.

I. Priority

Applicants point out that the Examiner mistakenly stated that the priority date for the instant application is May 15, 1999. However, the actual priority date is May 13, 1999. Applicants respectfully request that the Examiner acknowledge the effective filing date for the instant application to be May 13, 1999.

II. Claim Rejections Under 35 U.S.C. §§ 101/112

The Examiner has rejected claims 25-56 under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility due to its not being supported by either a specific and/or substantial utility or a well-established utility. In particular, the Examiner alleges, "claimed proteins ... are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any predicted polypeptide sequence that was derived from computational analyses of the cDNA sequence." *See* Paper No. 0703, page 4, lines 4-7. The Examiner further alleges that "the protein is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter." *See* Paper No. 0703, page 7, lines 3-4.

Applicants respectfully disagree and traverse.

Preliminarily, Applicants point out that claims 37-46 has been canceled, thus rendering the rejection to these claims moot. Applicants respectfully request withdrawal of the rejection to claims 37-46.

The Federal Circuit has characterized the standard for utility by indicating:

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. *See Brenner v. Manson*, 383 U.S. 519, 534 (1996); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger*, 120 F. 247, 275 (7th Cir. 1903) (the test for utility is whether the invention "is capable of serving any beneficial end").

Juicy Whip, Inc. v. Orange Bang Inc., 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999).

Furthermore, in order to find that an asserted utility is neither specific nor substantial, the burden is on the Examiner to make a *prima facie* case showing that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the Applicant to be specific or substantial. *See* M.P.E.P. § 2107.02(IV); Utility Examination Guidelines, 66 FR 1092, January 5, 2001 at 1098, col. 3 (emphasis added). The Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *See id.* Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not specific, substantial, and credible; (2) support for factual findings relied upon in reaching this conclusion; and (3) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See id* (emphasis added). In the instant case, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

On page 4 of Paper No. 0703, the Examiner provides an explanation as to why the claimed protein is not supported by a specific asserted utility. Specifically, the Examiner alleges that (1) the asserted utilities are generally applicable to any predicted polypeptide sequence that was derived from computational analyses of the cDNA sequence; (2) the asserted utilities are based on upon an analysis of the expression of nucleic acids in tissue distribution and not protein analysis; and (3) the cDNA itself is disclosed to potentially have errors.

In response, Applicants assert that the explanation and reasoning provided by the Examiner is immaterial with regards to utility – the question of utility is whether one of ordinary skill in the art would understand that a specific, substantial and credible utility has been asserted. It is unclear to Applicants how a protein was isolated (via computational analysis or otherwise) is relevant to the question of patentable utility. Secondly, when investigating the expression levels of a new gene and protein, those of ordinary skill in the art most often look to mRNA expression levels as predictive of the relative protein expression levels. Lastly, there is no evidence of any sequencing errors for the claimed invention – the claimed polypeptide is a full translation of a functional protein as indicated in Table 1 of the specification. Indeed, this is confirmed by Genbank Accession No. NP_054905, which shares 100% identity with the claimed polypeptide (submitted herewith as Exhibit A).

The Examiner has further provided generalized statements that utilities asserted for the polypeptide SEQ ID NO:225 are not useful because "no specific use has been indicated as the preferred embodiment of SEQ ID NO:225. In fact, the specification ... never connects the elected sequence to any particular or specific utility." *See* Paper No. 0703, page 6, lines 25-29. Contrary to the Examiner's allegation, Applicants have identified a specific use for SEQ ID NO:225, namely as a marker for testicular cancer and for the male reproductive system. *See* specification at page 97, lines 3-26. Furthermore, Applicants assert Reference AA, submitted April 17, 2003, corroborates Applicants' asserted utility. Applicants assert that scientific evidence may be used to corroborate Applicants' asserted utility. Legal precedent for the use of post-filing date references in this manner can be found in *In re Brana*, where the courts stated:

> The Kluge declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. *In re Marzocchi,* 439 F.2d at 224 n.4, 169 U.S.P.Q. (BNA) at 370 n.4.

In re Brana, 51 F.3d 1560 at 1567 n.19, 34 U.S.P.Q.2D (BNA) 1436 (March 30, 1995).

The test for specificity is whether an asserted utility is specific to the subject matter claimed, in contrast to a utility that would be applicable to the broad class of the invention, such as use of a complex machine for landfill. *See* Utility Examination Guidelines. The disclosed utilities for Protein HCUDW10 discussed above are specific, in that not every protein may be used to diagnose testicular cancer or disorders of the male reproductive system. Consequently, the skilled artisan would most certainly not consider such a use to be a "throw-away utility" such as landfill.

Applicants have previously provided support of their assertion that Protein HCUDW10 would be useful as a diagnostic marker for testicular cancer or disorders of the male reproductive system. Reference AA, Genseq ID AAY73899, states that this sequence is a human prostate tumor EST fragment derived protein #86. The amino acid sequence of Reference AA corresponds to SEQ ID NO:225. Since one or ordinary skill in the art would clearly recognize prostate cancer as being a disorder of the male reproductive system, Applicants have provided third party evidence which supports a reasonable correlation between Protein HCUDW10 and disorders of the male reproductive system.

In response to the Examiner's "laundry list" argument against a specific utility on page 6 of Paper No. 0703, Applicants point out that the disclosure of diseases and disorders

for the claimed polypeptide does not negate the specificity of any one of those uses. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention . . .". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id. See also, In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988). Nonetheless, Applicants have asserted a specific and substantial utility for the claimed invention – a differential marker for testicular cancer and disorders of the male reproductive system, *i.e.*, prostate cancer. Thus, the Examiner's assertions that the specification lacks specific utility because "this wishlist desire for utility for the claimed sequence falls short of a readily available utility" is improper and immaterial.

Finally, the M.P.E.P. defines a "substantial utility" as a utility with real world use. *See* M.P.E.P. § 2107.01. The M.P.E.P. further states in the same section, "An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a 'real world' context of use ...". Applicants assert in the specification, "polypeptides of the invention are useful as reagents for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of the diseases and conditions which include, but are not limited to, testicular cancer." *See* specification at page 97, lines 6-9. Accordingly, the utilities asserted by Applicants are clearly substantial.

In view of the above arguments, Applicants have provided evidence and reasoning which supports the Applicants' assertion of utility. In particular, Applicants have provided evidence that the polypeptides and/or antibodies raised against the polypeptide of the instant application are useful as a cancer diagnostic. This utility asserted in the specification for Protein HCUDW10 (SEQ ID NO:225) is indeed specific, substantial and credible. Accordingly, Applicants respectfully submit that the rejection of claims 25-36 and 47-56 under 35 U.S.C. § 101 has been obviated. Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged

lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

III. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

A. Written Description of Claims 25-56

Claims 25-56 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges:

> [t]he claims are directed to encompass proteins corresponding to sequences of 90% or 95% identity to the overall of SEQ ID NO:225. The specific 10% or 5% that are not identical to the elected sequence are represented by the claim are not supported by the specification. Although the sequence itself distinguishes the structural features of the nucleic acid, sequences, beyond exact identity (be it in entirety or to contiguous fragments) of the elected SEQ ID NO:225, are included but not disclosed as to written description. Each variation of the 5% or 10% non-identical results in a new and independent sequence that does not reliably result in similar or identical biological activities as result, for example, from altered folding patterns.

See Paper No. 0703, page 7, line 26 to page 8, line 4.

Preliminarily, Applicants point out that claims 37-46 has been canceled, thus rendering the rejection to these claims moot. Applicants respectfully request withdrawal of the rejection to claims 37-46.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02.

The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000), hereinafter referred to as "*Unocal.*" While the applicant must "blaze marks on trees," rather than "simply [provide] the

public with a forest of trees," an Applicant is not required to explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. *See also* M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."). The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added).

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is discharged if the Examiner can present evidence or reasons why one skilled in the art would *not* reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by the rejected claims in the present application as filed. Applicants further submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

Applicants submit that the deposit of cDNA encoding Protein HCUDW10 with the ATCC under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure with an International Depository Authority satisfies 35 U.S.C. § 112, first paragraph. Applicants have experimentally isolated the polynucleotides encoding the claimed polypeptides and have described in the specification how to isolate said polypeptide. *See* Example 1 of the specification. One of ordinary skill in the art would reasonably conclude that Applicants had possession of the claimed polypeptides.

In view of the above, Applicants respectfully assert that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. Moreover, the specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. Therefore, Applicants submit that the claims fully meet the written description requirements

of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of claims 25-36 and 47-56 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. Written Description of Claims 31-36, 42-46 and 52-56

Claims 31-36, 42-46 and 52-56 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has attempted to find support in the specification that demonstrates compliance and request that the Applicants identify in the specification that compliance with 37 C.F.R. §§ 1.801-1.809 has been met. Furthermore, the Examiner alleges that the specification does not provide sufficient written description to support the biological deposits of the claims.

Preliminarily, Applicants point out that claims 42-46 has been canceled, thus rendering the rejection to these claims moot. Applicants respectfully request withdrawal of the rejection to claims 42-46.

Applicants respectfully point out that the specification, as set forth in 37 C.F.R. § 1.809(d), clearly describes at page 9, first paragraph that the deposited clone contained in ATCC Deposit No. 209197 has been deposited under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, Virginia 20110-2209, U.S.A. The Applicants respectfully submit that the specification is in compliance with 37 C.F.R. §§ 1.801-1.809.

Nevertheless, Applicants submit herewith a declaration regarding availability of the deposit made in connection with the present application under the Budapest Treaty.

As attorney for the above-identified Applicants in the above-identified patent application, I hereby declare and state that:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was

made on July 3, 1997, accepted by the ATCC, and given ATCC Deposit No. 209197. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Deposit No. 209197 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b).

Applicants respectfully submit that ATCC Deposit No. 209197 is available to the public. Furthermore, the specification teaches one skilled in the art how to isolate the cDNA from the deposited sample. *See, e.g.,* Example 1 at pages 474-477. Thus, Applicants have adequately enabled one skilled in the art to make and use the claimed invention.

Applicants submit that the rejections under 35 U.S.C. § 112, first paragraph, have been obviated by the above declaration. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn for claims 31-36 and 52-56.

IV. Claim Objections

The Examiner has objected to claims 31-36, 42-46 and 52-56 for not further limiting the subject matter of claims 25-30, 37-41 and 47-51 respectively.

Preliminarily, Applicants point out that claims 42-46 has been canceled, thus rendering the objection to these claims moot. Applicants respectfully request withdrawal of the objection to claims 42-46.

With regards to the objections to claims 31-36 and 52-56, Applicants respectfully disagree and traverse the claim objection. Applicants point out that claims 31 and 52 are not dependent upon claims 25 and 47 respectively. Therefore it is unclear why the Examiner asserts that claims 31-36 and 52-56 do not further limit the subject matter of claims 25 and 47. Applicants further note that they are entitled to claim the invention using multiple claims, so long as the claim set as a whole clearly defines the subject matter of the invention. *See* M.P.E.P. § 2173.05(n). Furthermore, section 706.03(k) of the M.P.E.P. states:

> Inasmuch as a patent is supposed to be limited to only one invention or, at most, several closely related indivisible inventions, limiting an application to a single claim, or a single claim to each of the related inventions might appear to be logical as well as convenient. However, court decisions have confirmed applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough.

Applicants further note that it is routine and widely accepted in biotechnology patent practice to claim isolated proteins by an explicit recitation of the amino acid sequences as well as those isolated from a corresponding deposited clone. Thus, Applicants respectfully request that the objections to claims 31-36 and 52-56 be reconsidered and withdrawn.

Conclusion

Applicants respectfully request the amendments and remarks of the present response be entered and made of record in the present application. In view of the foregoing amendment and remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the allowance of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: November 10, 2003

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